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(4) Progress reports on studies underway every January 1 and July 1 until completion.

(c) Failure on the part of any sponsor to comply with any of the provisions of paragraph (b) of this section for any of the antibacterial drugs included in paragraph (b)(1) of this section, or interim results indicating a health hazard, will be considered as grounds for immediately proceeding to withdraw approval of that drug for use in animal feeds under section 512(l) of the act in the case of failure to submit required records and reports and under section 512(e) where new information shows that such drug is not shown to be safe.

(d) Criteria based upon the guidelines laid down by the task force may be obtained from the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(e) Reports as specified in this section shall be submitted to: Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Drug Evaluation (HFV-100), 7500 Standish Pl., Rockville, MD 20855.

(f) Following the completion of the requirements of paragraphs (a) and (b) of this section and the studies provided for therein:

(1) Those antibiotic, nitrofurantoin, and sulfonamide drugs which fail to meet the prescribed criteria for subtherapeutic uses but which are found to be effective for the therapeutic purposes will be permitted in feed only for high-level, short-term therapeutic use and only by or on the order of a licensed veterinarian.

(2) Animal feeds containing antibacterial drugs permitted to remain in use for subtherapeutic purposes shall be labeled to include a statement of the quantity of such drugs.

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any Type A medicated article which is produced solely from a Type A article that is in compliance with the requirements of this section: *Provided*, That the Type A medicated article contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where the Type A article is approved by regulation in this part.

(1) The following antibacterial Type A articles manufactured by the designated sponsors are eligible for interim marketing based on their compliance with the requirements of this section:

Drug sponsor	Type A article	Species	Use levels	Indications for use
Fermenta Animal Health Co.	Bacitracin methylene disalicylate.	Chicken turkeys, swine, and cattle.	Sec. 558.76	Sec. 558.76.

(2) [Reserved]

[51 FR 8811, Mar. 14, 1986; 51 FR 11014, Apr. 1, 1986, as amended at 51 FR 28547, Aug. 8, 1986; 53 FR 20843, June 7, 1988; 54 FR 37098, Sept. 7, 1989; 54 FR 51386, Dec. 15, 1989; 55 FR 8460, 8462, Mar. 8, 1990; 56 FR 41912, Aug. 23, 1991; 56 FR 64702, Dec. 12, 1991; 57 FR 6476, Feb. 25, 1992; 57 FR 8577, Mar. 11, 1992; 57 FR 14639, Apr. 22, 1992; 58 FR 17515, Apr. 5, 1993; 58 FR 30119, May 26, 1993; 61 FR 51589, Oct. 3, 1996; 64 FR 992, Jan. 7, 1999; 64 FR 37673, July 13, 1999; 71 FR 16221, Mar. 31, 2006; 75 FR 16002, Mar. 31, 2010]

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

§ 558.55 Amprolium.

(a) *Approvals*. Type A medicated articles: 25 percent to No. 016592 in

§ 510.600(c) of this chapter for use as in paragraph (d) of this section.

(b) *Special considerations*. Do not use in Type B or Type C medicated feeds containing bentonite.

(c) *Related tolerances*. See § 556.50 of this chapter.

(d) *Conditions of use*—

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(1) *Cattle*. It is used as follows:

Amprolium in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 11, 350; to provide 5 milligrams per kilogram of body weight per day.	Calves: As an aid in the prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Top-dress on or mix in the daily ration. Feed for 21 days when experience indicates that coccidiosis is likely to be a hazard, as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	016592
(ii) 113.5 to 11, 350; to provide 10 milligrams per kilogram of body weight per day.	Calves: As an aid in the treatment of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Top-dress on or mix in the daily ration. Feed for 5 days as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	016592

(2) *Chickens*. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5	Replacement chickens: For development of active immunity to coccidiosis.	Feed continuously until onset of production as follows:	016592

Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Amprolium in grams per ton	Amprolium in grams per ton	Amprolium in grams per ton
Severe exposure to coccidiosis	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis	72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 36.3 to 113.5	Bacitracin methylene disalicylate 4 to 50.	Replacement chickens: For development of active immunity to coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed according to subtable in item (i). Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 72.6 to 113.5	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> only.	Feed continuously as the sole ration; as sole source of amprolium.	016592
(iv) 72.6 to 113.5	Bambermycins 1 to 2.	Broiler chickens: For prevention of coccidiosis caused by <i>Eimeria tenella</i> only; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(v) 113.5	1. Laying chickens: For prevention of coccidiosis. 2. Laying chickens: For treatment of coccidiosis in moderate outbreaks.	Feed continuously as the sole ration; as the sole source of amprolium. Feed for 2 weeks.	016592
(vi) 113.5 to 227	1. Replacement chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired. 2. Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired.	Feed continuously from day-old until onset of production; as the sole source of amprolium. Feed continuously as the sole ration; as sole source of amprolium.	016592

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Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(vii) 113.5 to 227	Bambermycins 1 to 2.	Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(viii) 227	Laying chickens: For treatment of coccidiosis in severe outbreaks..	Feed for 2 weeks	016592

(3) *Turkeys*. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5	Bambermycins 1 to 4.	Growing turkeys: For prevention of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole source of amprolium; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(ii) 113.5 to 227	Turkeys: For prevention of coccidiosis.	Feed continuously as the sole ration; as sole source of amprolium.	016592

(4) *Pheasants*. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 159	Growing pheasants: For the prevention of coccidiosis caused by <i>Eimeria colchici</i> , <i>E. duodenalis</i> , and <i>E. phasiani</i> .	Feed continuously as sole ration. Use as sole source of amprolium.	016592
(ii) [Reserved]				

[41 FR 10985, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.55, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.58 Amprolium and ethopabate.

(a) *Specifications*. Type A medicated articles containing:

(1) 25 percent amprolium and 8 percent ethopabate or 5 percent amprolium and 1.6 percent ethopabate;

(2) 25 percent amprolium and 0.8 percent ethopabate or 5 percent amprolium and 0.16 percent ethopabate.

(b) *Approvals*. See No. 016592 in § 510.600(c) of this chapter.

(c) *Special considerations*. Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Related tolerances*. See §§ 556.50 and 556.260 of this chapter.

(e) *Conditions of use*. It is used in chicken feed as follows:

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) Amprolium 113.5 and ethopabate 3.6.	Broiler chickens: As an aid in the prevention of coccidiosis.	Feed continuously as sole ration; as sole source of amprolium. Not for laying chickens.	016592